OPO OPHTHALMIC & PHYSIOLOGICAL OPTICS
THE JOURNAL OF THE COLLEGE OF OPTOMETRISTS

Ophthalmic & Physiological Optics ISSN 0275-5408

VA LOVIT II: a protocol to compare low vision rehabilitation and basic low vision

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Citation information: Stelmack JA, Tang XC, Reda DJ, Stroupe KT, Rinne S & Massof RW. VA LOVIT II: a protocol to compare low vision rehabilitation and basic low vision. *Ophthalmic Physiol Opt* 2012, **32**, 461–471. doi: 10.1111/j.1475-1313.2012.00933.x

Keywords: low vision, low vision rehabilitation, reading rehabilitation, vision rehabilitation

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Trial registration: (ClinicalTrials.gov Identifier NCT00958360).
*The LOVIT study group is listed in Appendix.

Received: 20 March 2012; Accepted: 09 July 2012

Abstract

Purpose: To compare the effectiveness of low vision rehabilitation (LVR) and basic low vision (LV) in a single masked multicentre randomised controlled trial (RCT).

Methods: Three hundred and thirty patients eligible for US. Veterans Affairs (VA) healthcare services with primary eye diagnosis (better-seeing eye) of macular disease and best-corrected distance visual acuity of 0.40–1.00 logMAR (6/15 to 6/60 or 20/50 to 20/200 Snellen) are being enrolled at seven VA facilities. All participants receive an optometric LV examination; and they are eligible to receive the same LV devices that are provided without charge. In LVR, a LV therapist dispenses devices and provides 2 or 3 (1½ to 2½ h) therapy sessions with assigned homework to teach effective use of remaining vision and LV devices. Contact time with the therapist depends upon the devices prescribed and the patient's progress in learning the skills that are taught. In basic LV, devices are dispensed by the optometrist without LV therapy. Contact time for dispensing is one hour or less depending on LV devices prescribed. The primary outcome measure is a comparison of the changes in visual reading ability (estimated from patients' difficulty ratings of reading items on the VA LV VFQ-48 questionnaire) between the treatment and control arms from pre-intervention baseline to 4 months (2 months after completion of treatment). Secondary outcome measures are changes in overall visual ability, visual ability domain scores calculated from subsets of items (mobility, visual information processing and visual motor skills), Short Form-36, and Minnesota Low Vision Reading Test scores. Cost-effectiveness analysis will be conducted using VA LV VFQ-48 scores and QALYS computed from EuroQol scores.

Results: A total of 137 patients representing 41.5% of the study target of 330 patients were randomised from October 2010 to March 2012. Among those 137 patients, mean age was 80.2 (S.D. ± 9.9) years at enrollment; 97.1% of the patients were males; 94.2% were white. Mean best corrected VA was 0.65 (S.D. ± 0.3) logMAR (approximately Snellen 6/27 or 20/90) at baseline.

Conclusions: LOVIT II is the first multicentre RCT comparing the effectiveness and cost-effectiveness of LVR and basic LV for patients with macular diseases and near normal or moderate levels of visual impairment.

Introduction

As the populations of the US and Europe age and the prevalence of visual impairment increases, the demand for low vision (LV) services is expected to grow.[1,2] Chronic visual impairments restrict self-sufficiency and independence by reducing patients' ability to perform basic and instrumental activities of daily living as well as limiting their ability to socially interact with family and friends.[3–9] Patients with LV have an increased risk of depression,[10–13] injury [14–16] and a decline in general health.[17] Low vision services have the potential to restore functional abilities and potentially lower societal costs by reducing utilisation of health and social services and increasing independence and quality of life.[3] Studies comparing the effectiveness and cost-effectiveness of different LV service delivery models are needed to guide policy makers and to develop informed clinical practice guidelines.[3]

The Veterans Affairs (VA) Low Vision Intervention Trial (LOVIT) demonstrated the effectiveness of a new outpatient LV rehabilitation (LVR) program for legally blind veterans with macular diseases moderate and severe impairment with visual acuity between 0.70 and 1.40 logMAR (Snellen 6/30 to 6/150 or 20/100 or less to 20/500 or greater).[18–21] With the advent of anti-VEGF injections and other new treatments that delay and reverse the progression of macular disease, it is important to evaluate the outcomes of LV services that target the growing population of patients with macular diseases and near normal vision or moderate visual impairment. Low Vision Intervention Trial II (LOVIT II) will complement LOVIT by comparatively studying the outcomes of basic LV and LVR that are offered by the VA healthcare system to veterans with macular diseases and visual acuity from 0.40 to 1.00 logMAR (6/15 to 6/60 or 20/50 to 20/200 Snellen).

Methods

Trial objective and design

A single masked, randomised controlled trial (RCT) with a 1:1 randomisation between treatment and control arms is being conducted at seven VA medical centres in the US to compare the effectiveness of LVR to basic LV. The LOVIT II trial is registered with clinical trials.gov (Identifier NCT00958360) and it adheres to the CONSORT statement (http://www.consort-statement.org).

The patients and clinical staff providing LV services are not masked to patient treatment assignments. The interviewers use a script, approved by the institutional review board (ethics committee), to inform patients that they should not disclose their treatment group. Primary and secondary outcome data will not be shared with the investigators or clinical staff until the end of the study.

Specific aims

1 Compare the mean changes in patients' visual reading ability [estimated from patients' difficulty ratings of reading items on the 48 item VA Low Vision Visual Functioning Questionnaire (VA LV VFQ-48)][22–26] from pre-intervention baseline to 4 months (2 months after treatment) between the treatment and control groups.
2 Compare the mean changes in secondary outcomes [overall visual ability and other visual domain scores constructed from subsets of items (mobility, visual information processing, visual motor skills), Short Form-36 (SF-36)[27] and Minnesota Low Vision Reading Test (MNREAD)[28] scores] from pre-intervention baseline to 4 months (2 months after treatment) between treatment and control groups.
3 Identify the characteristics of patients who benefit from LVR and basic LV services by determining if the mean changes in VA LV VFQ-48 visual ability scores are predicted by baseline best-corrected visual acuity, reading rates on the MNREAD, presence of central scotomas, LV devices prescribed, baseline SF-36 scores, age over 80 years or presence of visual fluctuations.
4 Conduct an economic evaluation to compare the costs and cost-effectiveness of LVR and basic LV from pre-intervention baseline to 4 months (2 months after treatment).
5 Observe patients enrolled in the study after the trial ends to describe additional LV services received by these patients from 4 months to 1 year and to measure visual ability (reading, mobility, visual motor, visual information processing and overall) using the VA LV VFQ-48 at 1 year. Conduct exploratory analyses to compare mean changes in visual ability scores between the treatment and control groups.

Outcome measures

The primary outcome measure is changes in visual reading ability measured with the VA LV VFQ-48. Secondary outcome measures are changes in overall visual ability and the other visual ability domain scores calculated from subsets of VA LV VFQ-48 items (mobility, visual information processing and visual motor skills), SF-36 and MNREAD scores.

Visual reading ability was selected as the primary outcome because reading is one of the most frequently reported goals of patients with LV and most LV interventions target reading.[26] Clinicians often measure reading speed, independence or accuracy performing surrogate tasks (e.g., correctly reading a price tag or the amount due on a bill) to estimate LV patients' functional capabilities. However, measurements performed in clinical

settings may not provide an accurate estimate of the treatment's effect on tasks that patients perform in daily living. Measurements in everyday life are typically accomplished using patients' self-reporting of the difficulty they experience performing a range of selected daily activities.[3,19]

The VA LV VFQ-48 was developed by members of the research team to evaluate outcomes of LV clinical trials. It is valid, reliable and sensitive to changes in visual ability occurring after different levels of vision rehabilitation.[22,24,25] The VA LV VFQ-48 has been used in several studies of VA LV and blind rehabilitation services including the LOVIT.[18,29] Its use in LOVIT II facilitates comparisons with these studies.

Administration of questionnaires

All of the questionnaires (VA LV VFQ-48, SF-36, EQ-5D) are administered pre-intervention, at 4 months (2 months after treatment) and at 1 year. The VA LV VFQ-48 elicits patients' perception of the difficulty they have performing 48 activities.[22–26] Patients rate the difficulty of each item using the ordered response categories: (1) not difficult, (2) slightly/moderately difficult, (3) extremely difficult, and (4) impossible. The development and validation of the questionnaire have been reported previously.[22–26] The SF-36 is a generic quality of life instrument with eight subscales (physical functioning, physical role limitations, bodily pain, vitality, social functioning, emotional role limitations, mental health and general health) that was developed for patients to self-report their health status.[27] The EuroQol (EQ-5D) is a measure of health outcomes that includes five attributes (mobility, self-care, usual activity, pain/discomfort and anxiety/depression).[30] The EQ-5D also includes a 20-centimetre visual analogue scale for the self-assessment of current general health.[30]

Participants

Subjects will be 330 veterans recruited from VA medical care facilities in Baltimore, Maryland; Cincinnati and Dayton, Ohio; Hines, Illinois; Milwaukee and Madison, Wisconsin; and Philadelphia, Pennsylvania. The inclusion and exclusion criteria are presented in *Tables 1 and 2*. The inclusion/exclusion criteria were chosen to enrol patients with chronic, uncorrectable visual impairments that impact central vision of both eyes who would be referred to low vision services because they are expected to react positively to treatment that emphasises visual enhancement. Patients with visual fields constricted to <20 degrees are excluded because these patients would usually be referred to blind rehabilitation for training to use other senses and non-visual devices that are not offered in LOVIT II.

Anti-VEGF injections and other new treatments are currently widely available to delay and or reverse the progression of macular diseases. It is important that patients who are receiving these treatments be included so that the study findings can be generalised to the larger population of veterans with macular diseases. The exclusion criteria for patients undergoing macular disease treatment were selected after consultation with retina specialists to exclude patients who were expected to experience a significant improvement in vision as a result of medical or surgical treatment.

Table 1. Low Vision Intervention Trial II inclusion criteria

Inclusion Criteria
Enrolled in US VA healthcare system
Primary eye diagnosis (better-seeing eye) of any macular disease
Best-corrected distance visual acuity in the better-seeing eye of 20/50 to 20/200*

*The better-seeing eye is defined as the eye with the better visual acuity. If visual acuity is equal in both eyes, the better-seeing eye is identified as both eyes.

Table 2. LOVIT II exclusion criteria

Exclusion Criteria
Does not have a telephone
Does not speak or read English at fifth grade level or above
Has previously received LVR*
Failed TICS screening with a score equal to or <30
Unable or unwilling to attend clinic visits required for the study
Has severe hearing impairment that interferes with participation in telephone questionnaires
Has other health conditions that preclude follow-up
Has visual field in better-seeing eye <20 degrees in diameter
Has vitreous hemorrhage affecting line of sight
Plans cataract extraction in the next 4 months
Is currently receiving treatment for macular disease (laser, medical or surgical therapy) that is expected to improve vision as a result of treatment[†,‡,§]
Is currently participating in another study and participation in LOVIT II was not approved in writing by local site investigator and/or principal investigator of both studies

LOVIT, Low Vision Intervention Trial; LVR, low vision rehabilitation; TICS, Telephone Interview for Cognitive Status.
*Has not experienced vision loss since previous LVR.
[†]Has serous/hemorrhagic detachment of macula, or choroidal neovascular membrane (CNVM), and is being treated by injection, and has had <3 injections prior to screening visit.
[‡]Has diabetic macular edema (DME) and is being treated with injections or laser, and first treatment was <2 months prior to screening visit.
[§]Has diabetic macular edema, and topical non-steroidal anti-inflammatory drugs (NSAIDS) started or last triamcinolone acetonide (IVTA) injection given <3 months prior to screening visit.

Recruitment

The flow of participants through the trial is described in *Figure 1*. Patients with macular diseases who meet inclusion criteria are identified through a review of medical eye examinations located in electronic medical records. The US VA restricts recruitment of research subjects by telephone. Patients receive information about the study from health care providers during clinical visits or through an information letter that is sent by mail with a return postcard for patients to indicate whether or not they want to be contacted by the research coordinator. Informed consent and the Health Insurance Portability and Accountability Act Authorization, a signed consent for the release of the health information that is collected in the study, are obtained from those who agree to enrol. A screening is conducted to determine eligibility.

Screening

Literacy is evaluated using the DOLCH word test.[31] A list of frequently read words is used to estimate reading grade level. A person who reads at US 5th grade level (approximately 10–11 years of age) or higher is considered to be literate. The Telephone Interview for Cognitive Status (TICS) is a standardised test to detect cognitive impairment in seniors that correlates highly with the Mini-Mental Examination.[32] The TICS is often used in assessing cognitive status of visually impaired persons because pens and pencils are not used and it is easily administered on the phone or in person. Best-corrected visual acuity is measured for each eye separately using the Early Treatment of Diabetic Retinopathy Study (ETDRS) visual acuity chart after refraction is performed by an optometrist.[33] The EDTRS chart has five letters per line. A line is counted as read when more than half of the line is read correctly. The logMAR conversion to Snellen equivalent is recorded from the chart. Patients who do not meet eligibility criteria are not randomised. Baseline demographic data and medical history are collected from patients eligible for randomisation. *Table 3* summarises the demographic and health status information that is collected from patients by study coordinators. Response choices, except age, are multiple choices with yes or no options.

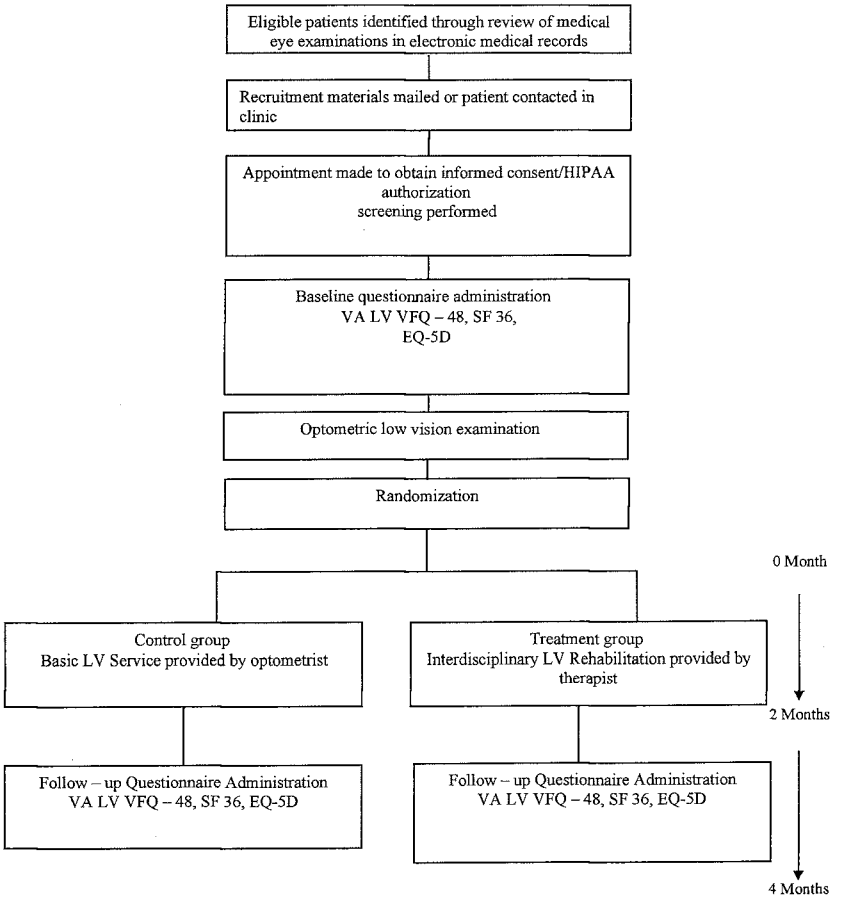

Figure 1. Describes the flow of participants through each stage of VA Low Vision Intervention Trial II.

Table 3. Demographics and health screening

Demographics and Health Screening
Age
Gender
Ethnicity
Race
Education (highest level)
Living situation
Employment status Income
Health insurance (other than VA)
Health information (derived from a list of health conditions)
Use of assistive devices for mobility
Description of hand strength
Hand problems
Motion limitations
Endurance limitations
Description of memory
Age when vision loss started
Fluctuations in vision
Eye disease treatments received in last year
Hearing loss and use of hearing aids

Table 4. Low Vision Intervention Trial II low vision examination

Low Vision Examination
Patient history (ocular, medical, social, functional)
Assessment of patient's needs and goals
Visual acuity measurement using EDTRS chart and Lighthouse Near Visual Acuity Test
Eccentric viewing assessment using Face Fields
Refraction
Contrast sensitivity testing using Pelli Robson Chart
Central visual field assessment using the Johns Hopkins University and Erickson Vision Test
Ocular motility and binocular vision assessment
Measurement of reading acuity, critical print size and maximum reading rate using MNREAD
Low vision device evaluation
Ocular health assessment

Administration of baseline questionnaires

The site coordinator contacts the study chair's office to arrange for masked interviewers located in the study chair's office to administer the baseline questionnaires (VA LV VFQ-48, SF-36, and EuroQol) by telephone.

LV Evaluation and treatment planning

The LV examination is conducted according to Optometric Clinical Practice Guidelines for Care of the Patient with Visual Impairment published by the American Optometric Association.[34] A summary of the procedures that are included is provided in *Table 4*. The LV examination is conducted prior to randomisation to eliminate bias in prescription of LV treatment that may occur if the optometrist knows the patient's treatment assignment.

Randomisation

Prior to the start of patient recruitment, the statistician developed a randomisation scheme, a permuted block randomisation with random block sizes. Randomisations are stratified by participating site and baseline visual acuity measured by the optometrist after refraction.

Study personnel at the sites do not have access to the randomisation scheme. The site coordinator receives the assignment for each patient only after informed consent is obtained, a screening is conducted, the baseline questionnaires are administered, the LV examination is completed, and the patient is determined to be eligible for randomisation. The assignment is obtained from an online randomisation system built by the data coordinating centre.

Treatment

The treatment provided for patients in both arms of the trial is summarised in *Table 5*. Treatment begins on the same day as the low vision exam whenever possible. Treatment is delayed in some circumstances if the low vision devices prescribed by the optometrist are not in stock at the clinic. Low vision devices that are out of stock can usually be obtained in a week or two. Patients randomised to the basic LV are offered LV therapy after the final outcomes measurements are completed at 4 months (2 months after treatment).

Low vision rehabilitation

Each patient assigned to LVR should be able to demonstrate to the therapist independent and safe use of LV device(s) to meet identified goals. Contact time with the therapist depends upon the devices prescribed and the patient's progress in learning the skills that are taught. Therapy and homework manuals help ensure consistency of the treatment across sites. The lessons included in the LV therapy protocol are summarised in *Table 6*.

LV therapy for patients who do not have central fixation begins with the development of eccentric viewing skills using the recommended spectacle prescription for best visual acuity. The objectives of eccentric viewing training are (1) for the patient to understand the purpose and advantages of eccentric viewing and the location of his/her best viewing position, and (2) for the patient to efficiently use eccentric viewing to scan and sight-read words through

Table 5. Main components of the intervention provided in the two arms of Low Vision Intervention Trial II

Basic Low Vision	Low Vision Rehabilitation	Low Vision Devices Available for Both Groups
Optometry LV examination	Optometry LV examination	Daily wear glasses
LV devices dispensed by optometrist	LV devices dispensed by therapist	Filters to control glare
Contact time for dispensing visit is one hour or less	2–3 LV therapy sessions (1½ to 2½ h each) provided by therapist	Reading glasses
Contact time depends on LV devices prescribed	Contact time depends on LV devices prescribed and patient's progress in therapy	Hand held and stand magnifiers
LV devices provided without charge	LV devices provided without charge	Desktop or portable electronic magnifiers
LV therapy is offered after the trial ends 4 months from pre-intervention baseline		Intermediate distance devices (Optivisor or Max detail)
		Sports glasses
		Monocular telescopes
		Non-optical devices

LV, low vision.

Table 6. Low vision therapy available in Low Vision Intervention Trial II*

Low Vision Therapy Available
Eccentric viewing training
Near vision spot reading with pocket magnifier
Environmental modifications/non-optical aids
Portable, sustained reading with an illuminated stand magnifier
Sustained reading with reading glasses
Portable electronic magnifier
Sustained near vision tasks with Desktop CCTV
Sustained distance viewing with teleloupes
Spotting distance objects with monocular telescope
Learning to use an Optivisor
Learning to use a Max Detail
Integration of low vision devices into lifestyle

*Therapy provided for individual patients depends on the patient's needs and goals, the low vision devices prescribed and indications for eccentric viewing.

use of effective saccades.[20] A computer monitor is used to present practice exercises during therapy.

Every patient randomised to LV rehabilitation receives a homework envelope that contains the homework materials and the directions for completing assignments. Homework is assigned at each lesson, turned in and reviewed with the therapist at the next session. The homework review encourages patients' compliance with completion of their homework. The homework assignments are intended to enhance efficiency and confidence, to improve carryover skills by having the patients practice everyday tasks at home, to demonstrate a large variety of potential uses for a particular low vision device, and to identify problems and develop competence so that decisions or techniques will not be burdensome to apply.[20] Examples of homework include: (1) practice use of eccentric viewing by reading the indices on playing cards, (2) using a pocket magnifier to read an Italian restaurant take-out menu and record the price of the spaghetti entrée, and (3) reading a business letter and recording answers to questions about its contents. Copies of the LOVIT II Therapy and Homework Manuals can be obtained from the corresponding author or online at http://www.lowvisionproject.org.

Administration of follow-up questionnaires

The research plan is to administer the follow-up questionnaires (VA LV VFQ-48, SF-36, and EQ-5D) 4 months from the pre-intervention baseline (2 months after treatment). If completion of the LV treatment is delayed, e.g., patient illness or a long delay in obtaining LV devices that are not in stock, the follow-up time is adjusted on a case by case basis to occur approximately 2 months after the completion of treatment.

Data collection, management and quality control

The Hines VA Cooperative Studies Program Coordinating Center has the primary responsibility for data collection and management. Its staff collect, edit, store, and analyse data entered by the clinical centres via the VA electronic data capture system. Data quality control is monitored through a built-in data checking system. Acceptable ranges for the data were established at the start of the study. Out of range, overdue forms and missing data are tracked in the electronic data capture system. Overdue reports and inquiries for each site are generated monthly. Multiple statisticians review data summaries and analysis; interviewers periodically recheck questionnaire data entry. Study quality factors such as mis-randomisations,

treatment non-compliance (e.g., homework not turned in) and protocol deviations are reported. Masking disclosures are tracked and reported as protocol violations. Monthly recruitment, comparisons with recruitment goals and withdrawals are also reported. Serious adverse events and protocol violations are reported to the principle investigator immediately via email once the event is entered into the electronic data capture system. A data monitoring committee composed of members who are independent from the planning and conduct of the study was appointed with approval from the sponsor, VA Rehabilitation Research and Development Service. The data monitoring committee provides interim, independent and unbiased reviews of the study's ongoing progress.

Data analysis

All analyses will be based on intention to treat principles and will include all randomised patients. The last observation carried forward method will be used in analysis of the primary and secondary outcomes if the outcome values are missing. All patients who discontinue treatment will be encouraged to complete the post-rehabilitation questionnaires at the conclusion of the study. All statistical tests will be two-sided using an alpha of 0.05. Patient baseline characteristics will be compared by treatment group. Characteristics of patients in each group who withdraw early will be compared with those who complete the study to evaluate possible bias due to withdrawal from the study. No subgroup analyses are planned.

Rasch analysis will be performed on the VA LV VFQ-48 scores to estimate scores (person measures) on an interval scale from the ratings to each item.[19,22] Primary analysis will compare the mean change in VA LV VFQ-48 visual reading ability scores between the LVR treatment and basic LV control groups using a *t*-test for independent groups. Rasch analysis will be performed on the SF-36 responses to estimate scores on an interval scale from the ratings to each item. The *t*-tests for independent groups will be used to compare the mean changes in the secondary outcome measures [other VA LV VFQ-48 scores (overall visual ability, mobility, visual information processing and visual motor skills), SF-36 and MNREAD scores] between the two groups. Analysis of covariance (ANCOVA) will be also performed to compare mean changes in the outcomes between the two arms adjusting for baseline visual abilities and any imbalance in baseline variables.

Regression models will be used to determine if the mean change in VA LV VFQ-48 visual reading ability scores from pre-intervention baseline to 4-months can be predicted by baseline measures of visual impairment (best corrected visual acuity, presence of central scotomas), maximum reading rate on MNREAD pre and post-rehabilitation, age over 80 years, presence of visual fluctuations, life state measures (baseline SF-36 scores) and/or baseline visual ability.

Economic analysis

The cost analysis will identify the costs associated with LVR and basic LV. We will also compare the costs and consequences (in terms of functional visual ability) between LVR and basic LV. We will measure direct healthcare costs of the interventions from the healthcare provider's (i.e., VA's) perspective. We will measure consequences as the change in functional visual ability (i.e., change in VA LV VFQ-48 scores) from pre-intervention baseline to 4 months later (2 months after treatment).

Additionally, we will conduct a cost-effectiveness analysis.[35] We will assess total direct healthcare costs and total vision-related costs from randomisation to the 4 month follow-up. We will assess effectiveness using two measures of health-related quality of life (HRQoL): VA LV VFQ-48, which provides a condition-specific assessment of the visual function domain of HRQoL and QALYs, which provide a generic assessment of overall HRQoL. To compute QALYs, EQ-5D index scores will be obtained at pre-intervention baseline and at 4 months and will be converted into utility weights based on US population preferences.[30] These utility weights range from −0.11 for the worst EQ-5D index score to 1.0 for the best on a scale where 0.0 = death and 1.0 = perfect health. The utility weights will be connected with straight lines to construct the quality-adjusted survival curves, and QALYs will be computed from the area under this curve using the trapezoid rule.

To assess cost-effectiveness at 4 months, we will calculate the difference in average total costs and the difference in average effectiveness between LVR and basic LV. We will then assess the trade-offs between costs and effectiveness by calculating the cost per unit improvement in effectiveness (i.e., the difference in average costs divided by the difference in average effectiveness) giving an incremental cost-effectiveness ratio.

Although changes in utilisation of health care and social services are useful ways of demonstrating the economic benefit of LV interventions, they are not included in the LOVIT II plan for economic analysis. The primary outcome measure for LOVIT II is administered 4 months from baseline (2 months after treatment). The follow-up time in this study is likely too short to measure significant changes in utilisation of these services.

Exploratory analysis

Patients enrolled in LOVIT II will be observed after the trial is completed to describe additional low vision or

blind rehabilitation received by these patients and to measure visual ability (reading, mobility, visual motor, visual information processing and overall) with the VA LV VFQ-48 at 1 year. Analyses will be conducted to compare mean visual ability scores estimated from the VA LV VFQ-48 at pre-intervention baseline, 4 months and 1 year, and treatment effects using longitudinal analysis between the treatment and control groups; to compare mean changes in visual ability from pre-intervention baseline to 1 year between the two groups; and to compare pre- vs post-intervention changes in each arm in visual ability from pre-intervention baseline to 4 months, 4 months to 1 year and from pre-intervention baseline to 1 year.

Sample size

Assuming a small treatment effect size (ES) of 0.35 (referring to difference between treatment and comparison group change score distributions), setting the alpha error at 5%, power at 85%, and using a two sided *t*-test for 2 independent groups, a sample size of 300, 150 for each group, is required. Assuming a 10% withdrawal rate (death, loss to follow-up, withdrawal of consent) based upon previous studies, 330 patients (165 per group) will need to be randomised.

There is a strong linear trend between visual ability (in logits) and visual acuity (in logMAR units).[19,36] Using the LOVIT standard deviation (S.D.) of 0.93 logit and an ES of 0.35, a 0.33 logit change is comparable to a change of 2.5 lines of visual acuity on an EDTRS chart. A 2.5 line change would be considered clinically significant. A 2 to 3-line change is often used as an endpoint in ophthalmological randomised clinical trials and epidemiological studies.

Ethics approval

The study conforms to the tenets of the declaration of Helsinki. The protocol and written informed consents were approved by the VA Central Institutional Review Board.

Results

Before recruitment began, training and certification of study personnel took place in a two day meeting in Chicago. Recruitment started in October, 2010. A total of 209 patients were pre-screened by chart review; 54 were excluded. The remaining 155 patients were consented and screened in person. Among 155 screened patients, 137 (88.4%) were eligible for randomisation and 18 were excluded due to ineligibility. The most frequent reason for exclusion was a best-corrected visual acuity in the better-seeing eye after refraction that was out of the required range for the study. As of March 2012, a total of 137 patients were randomised, representing 41.5% of the study target of 330 patients. Among those 137 patients, mean age was 80.2 (S.D. ± 9.9) years at enrolment; 97.1% of the patients are males; 94.2% are white. Mean best corrected VA was 0.65 (S.D. ± 0.3) logMAR (approximately Snellen 6/27 or 20/90) at baseline.

Discussion

Binns *et al.*[3] conducted a systematic review to determine the effectiveness of LV services. They found that it is difficult to make comparisons across LV effectiveness studies due to the differences in measurement resolution of the various self-report instruments, scoring algorithms used and follow-up time; differences in visual impairment severity, diagnoses or other patient traits; differences between studies in treatment protocols; and differences between studies in acquisition of devices by patients and/or the types of LV devices dispensed.[3]

Three studies reported in the literature have compared optometric and multidisciplinary or enhanced LV service models and found no difference in outcomes.[3] In a single centre RCT conducted in the United Kingdom, Reeves *et al.*[37] evaluated the benefits of LV service delivery models (standard optometric LV, standard optometric LV plus a home based rehabilitation intervention and an attention control group consisting of the standard optometric LV plus supplementary home visits conducted by a community care worker who was not trained in LVR). Vision-specific HRQoL measured with the Vision Quality of Life Measure (VCM1)[38] at 12 months was the main outcome measure. No significant benefits were observed for any of the service delivery models. The authors commented that 'the outcomes may have been limited by the use of the VCM1, an outcome measure weighted to psychological aspects of visual impairment rather than performance of everyday activities'.[37]

Controlled before and after designs were used by de Boer *et al.* in the Netherlands and La Grow in New Zealand to compare the outcomes of basic and multidisciplinary or comprehensive LV services.[39–41] Differences in outcomes were not reported in either study. Most recently, Pearce *et al.*[42] conducted a single centre RCT to compare the outcomes of a standard optometric LV assessment with or without a second follow-up visit focused on use of LV devices. While patients self-reported less difficulty performing daily activities after an optometric low vision assessment, there was no further improvement when an additional training visit was provided. Hand-held and stand magnifiers were the LV devices that

were provided most frequently. The authors proposed that 'the simple nature of the devices prescribed' may explain the outcomes.[42] Eccentric viewing training was not provided.

LOVIT II is the first multicentre RCT to compare the effectiveness and cost-effectiveness of LVR and basic LV services for patients with macular diseases and near normal or moderate levels of visual impairment. Although the patients in LOVIT II will have access to electronic magnifiers and eccentric viewing training, we expect that the treatment effects in LOVIT II will be smaller than those in LOVIT due to differences in visual impairment severity. The LOVIT study enrolled patients with moderate or severe vision loss. Due to the severity of their vision loss, patients had high rehabilitation potential or room for improvement in visual function. The mean overall visual ability at baseline for the LOVIT treatment group was 0.35 (S.D. ± 0.9) logit. The LOVIT II study is enrolling patients with higher visual function and less rehabilitation potential or room for improvement in visual function. We do not know if the change in visual reading ability scores measured with the VA LV VFQ-48 will be greater for patients who receive LVR than for patients who receive basic LV.

Acknowledgements

Funding for this research was provided by the Department of Veterans Affairs Rehabilitation Research and Development Service grant C958R.

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Appendix

The LOVIT II study group

Chair's Office: Joan Stelmack OD, MPH, Principal Investigator, Edward Hines, Jr. VA Hospital, Robert W Massof, PhD, Co-Investigator, Wilmer Eye Institute, Johns Hopkins University School of Medicine.

Nancy Ellis MS, National Coordinator, Interviewer, Clement J. Zablocki VAMC, Stephen Rinne MS, Interviewer, Edward Hines, Jr. VA Hospital, Timothy Korwin, BS, Interviewer, Edward Hines, Jr. VA Hospital.

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